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John D. Vandermosten, CFA
312-265-9588 / jvandermosten@zacks.com

scr.zacks.com **10 S. Riverside Plaza, Suite 1600, Chicago, IL 60606**

Lantern Pharma, Inc. (LTRN: NASDAQ)

LTRN: 2Q:23 Quarterly Update

Our approach uses a DCF model and a 15% discount rate for valuation. Our model applies a 25% probability of ultimate approval and commercialization for LP-300 in never-smoker NSCLC, for LP-184 in multiple tumors in combination with ADCs and as monotherapy in ATRT. The model includes contributions from the United States, EU and rest of world.

Current Price (8/9/2023)	$4.67
Valuation	**$26.00**

OUTLOOK

Lantern Pharma uses AI & data to identify drug responders, uncover mechanism of action & rescue failed drugs. It is developing LP-300 for non- & never smoker NSCLC in the Harmonic trial. Secondary candidates include LP-100 for mCRPC which was reacquired from Allarity Therapeutics, and LP-184 and LP-284 which are in preclinical development for multiple biomarker-defined tumors and hematological cancers, respectively.

Lantern uses AI & machine learning to rescue failed and abandoned compounds by predicting response in biomarker-defined subpopulations. RADR is the firm's AI platform which analyzes proprietary, curated data to identify new candidates, mechanisms of action & patients most likely to respond to drug therapy, de-risking clinical trials and saving time and cost.

Lantern launched its Ph2 trial for LP-300 in never-smoker NSCLC in late 2022. We expect it to lead into a Ph3 study that will generate registrational data in 2025, US & EU regulatory submission in 2026 & commercialization in 2027. LP-184 is expected to begin Ph2 trials in defined advanced tumors in 2022.

SUMMARY DATA

52-Week High	**6.59**
52-Week Low	**4.05**
One-Year Return (%)	**-16.0**
Beta	**0.6**
Average Daily Volume (sh)	**43,803**
Shares Outstanding (mil)	**10.9**
Market Capitalization ($mil)	**50.9**
Short Interest Ratio (days)	**2.8**
Institutional Ownership (%)	**24.5**
Insider Ownership (%)	**17.5**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**N/A**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2023 Estimate	**N/A**
P/E using 2024 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**Above Average**
Type of Stock	**Small-Growth**
Industry	**Med-Biomed/Gene**

ZACKS ESTIMATES

Revenue

(In millions of US$)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2022	$0.0 A	$0.0 A	$0.0 A	$0.0 A	$0.0 A
2023	$0.0 A	$0.0 A	$0.0 E	$0.0 E	$0.0 E
2024					$0.0 E
2025					$0.0 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2022	-$0.38 A	-$0.41 A	-$0.21 A	-$0.31 A	-$1.31 A
2023	-$0.36 A	-$0.44 A	-$0.43 E	-$0.50 E	-$1.72 E
2024					-$2.01 E
2025					-$2.02 E

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What's New?

Second Quarter 2023 Financial and Operational Results

On August 9, 2023, Lantern Pharma, Inc. (NASDAQ: LTRN) announced 2Q:23 financial and operational results, filed its Form 10-Q with the SEC and hosted a video webcast to review accomplishments. Since the beginning of the second quarter, Lantern has further enrolled its Phase II Harmonic study, developed a collaboration with Bielefeld University and received clearance for its LP-184 study in solid and CNS tumors. Other important achievements year to date include creation of the Starlight Therapeutics subsidiary, multiple conference presentations of new data, expansion of the clinical leadership team, and creation of a roadmap for ADC development.

Highlights for 2022 and to-date include:

- Orphan drug designation for LP-284 in mantle cell lymphoma – January 2023
- AI collaboration with TTC Oncology – February 2023
- Addition of Dr. Reggie Ewesuedo M.D., VP of Clinical Development – March 2023
- Formation of Starlight Therapeutics – March 2023
- Refined direction for LP-100 with PARPi in prostate cancer – March 2023
- First patient dosed in Harmonic trial – March 2023
- ADC collaboration with Bielefeld University – June 2023
- IND clearance for LP-184 – June 2023
- Publication of LP-284 data in Oncotarget – June 2023

Lantern generated no revenue in 2Q:23 and incurred operating expense of $5.2 million, producing a net loss of ($4.7) million or ($0.44) per share.

For the quarter ending June 30, 2023 and versus the same comparable prior year period:

- Research & development expenses totaled $3.6 million, rising 19% from $3.0 million on account of greater research study expenditure and increases in payroll and compensation. These amounts were offset by decreases in product candidate manufacturing expenses and lower consulting expenses;
- General & administrative expenses were $1.6 million, rising 16% from $1.4 million. The following expense categories drove the increase: payroll and compensation, other professional fees, business development, travel expenses, legal and patent expense and rent. These amounts were partially offset by lower corporate insurance costs;
- Interest income was $118,000 versus $55,000 while other income was $326,000 versus a loss of ($153,000). Increases in dividend income, tax incentives from Australia, and a reduction in foreign currency loss contributed to the change;
- Net loss was ($4.7) million, or ($0.44) per share, compared to ($4.5) million, or ($0.41) per share.

At the end of 2Q:23 cash and marketable securities on the balance sheet totaled $47.9 million, declining $7.2 million over the six months since year end 2022. Cash burn for 2Q:23 was ($3.6) million versus ($2.7) million in the prior year period. No financing cash flows were recorded in 2Q:23 or in 2Q:22.

Harmonic Trial

In July 2022, Lantern announced the start of the Harmonic trial that will evaluate LP-300 in never smokers with non-small cell lung cancer (NSCLC). 90 subjects are expected to enroll in the Phase II study at 15 to 20 sites around the United States with enrollment expected to last from 12 to 16 months. It will target never smokers with lung adenocarcinoma who have relapsed after treatment with tyrosine kinase inhibitors (TKIs). The study will consist of two stages, the safety lead-in stage and the randomization stage. Patients on LP-300 + pemetrexed and carboplatin will be measured against patients on pemetrexed and carboplatin only in a 2:1 ratio. Primary endpoints are progression free survival (PFS) and overall survival (OS). Secondary endpoints include objective response rate

(ORR), duration of objective response (DOR) and clinical benefit rate (CBR). The trial will also collect liquid biopsies and acquire genomic and transcriptomic data from patients.

A March 28th, 2023 press release announced that the first patient in the trial had been dosed, kicking off the Phase II effort led by lead principal investigator Dr. Joseph Treat of Fox Chase Cancer Center. Lantern has activated five clinical trial sites including Gabrail Cancer Center, Northwest Oncology, New York Cancer and Blood Specialists, Texas Oncology and Cancer and Blood Specialty Clinic. Further trial sites across the United States and Asia are expected, especially in regions where never-smoker NSCLC are prevalent. Enrollment is anticipated to take 18-24 months.

Lantern expects to report details from the first stage of Harmonic as they become available. Genomic and transcriptomic data collected from subject biopsies will be used to further refine subject identification and potential responders. Investigators have identified a higher incidence of low PD-L1 expression in responders, highlighting this as an important marker and potential signature for identifying LP-300 candidates.

Exhibit I – Phase II HARMONIC Trial[1]



LP-284 Progress

Patent Notice of Allowance
The United States Patent and Trademark Office (USPTO) issued a notice of allowance[2] for patent application 17/192,838 entitled Illudin analogs, uses thereof, and methods for synthesizing the same. The composition of matter patent covers LP-284. Examples in the application include novel synthetic routes to prepare illudin derivatives and an illudin derivative presenting a positive optical rotation, which has therapeutic value. The molecule is intended to be used in non-Hodgkin's lymphomas and potentially other hematological malignancies. A Phase I trial is planned for later in 2023 with the LP-284 candidate. Lantern expects the resulting LP-284 patent will be Orange Book-listable with an anticipated expiration of early 2039. Similar patent rights are expected to be obtained for LP-284 in Europe, Japan, India, China, Australia, Canada, and Korea.

Orphan Drug Designation for LP-284 in MCL
Starting off the year with positive news, Lantern's first press release for 2023 announced the FDA's grant of orphan drug status to LP-284 in mantle cell lymphoma (MCL). According to the National Organization for Rare Disorders (NORD), MCL is a type of non-Hodgkin's lymphoma that affects every one out of 200,000 individuals or about 1700 persons. Lantern plans to file a related IND for LP-284 in B-cell non-Hodgkin's lymphomas, including MCL by mid-2023.

Orphan drug designation grants several benefits to awardees including tax credits for qualified clinical trials, exemption from user fees and seven years of exclusivity after approval. In the United States, the status may be given to products that address diseases affecting fewer than 200,000 persons. Similar benefits are available in other regions outside the United States, and ten years of exclusivity is offered in the European Union. These incentives may be available if Lantern seeks and is granted orphan designations in these areas. This is the fourth orphan designation granted to Lantern with others for indications in malignant gliomas, atypical teratoid rhabdoid tumors and pancreatic cancer.

LP-184 Progress

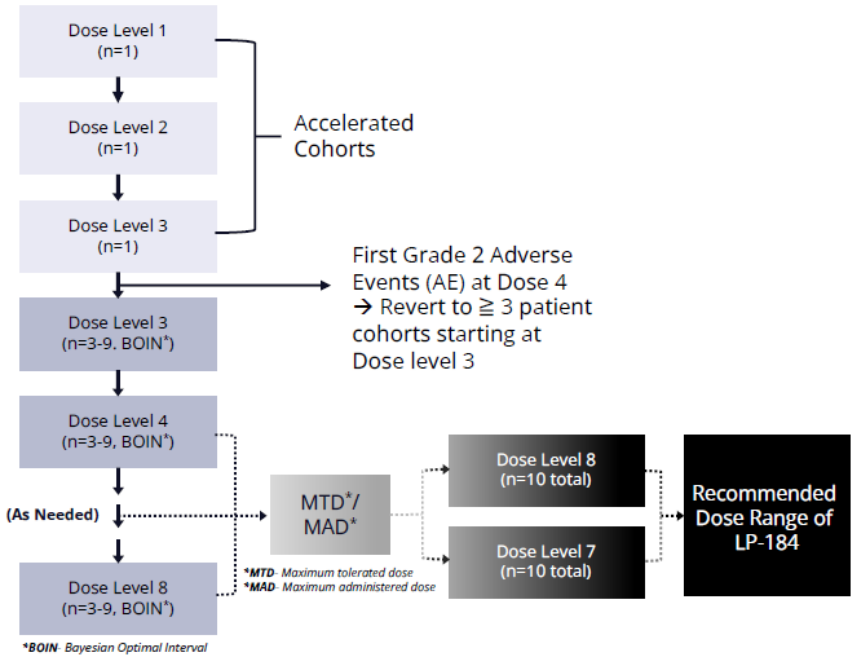
In mid-January 2023, Lantern announced the receipt of feedback from the FDA regarding its anticipated LP-184 investigational new drug (IND) submission. A June 12th press release memorialized the FDA's clearance of the IND application for LP-184 in solid tumors. As of the 2Q:23 quarterly report date, the Phase Ia study has now activated initial clinical sites and should begin screening subjects with multiple advanced solid tumors and brain and central

[1] Source: Lantern Pharma 2Q:23 Corporate Presentation, August 9, 2023
[2] A patent notice of allowance is an official notification from a patent examiner indicating that a patent application has been approved for issuance as a patent. The notice indicates that the patent examiner has reviewed the application and found that it meets the legal and technical requirements for patentability.

nervous system (CNS) cancers. A clinicaltrials.gov entry was created under the National Clinical Trial identifier NCT05933265. Up to 36 subjects are anticipated to be enrolled in the trial which is expected to be complete by the first half of 2024. Upon successful completion, Phase II studies in multiple solid tumor indications will be pursued by Lantern and brain and CNS indications will be pursued by Lantern's subsidiary, Starlight Therapeutics.

The goals of the trial are to evaluate the safety, tolerability, maximum tolerated dose (MTD) and identify a dose to be used in the anticipated Phase II trial. Eligible patients will be enrolled to receive LP-184 treatment at a dose determined based on the available cohort at the time of his or her enrollment. Patients will receive LP-184 infusion during Day 1 and Day 8 of each 21-day cycle, for a minimum of two cycles. Subjects will be monitored for safety, pharmacokinetics and clinical activity. Dose escalation is planned with a minimum of three patient cohorts (starting at dose level 1). After selection of the MTD, additional patients will be enrolled at two dose levels, including the MTD, as determined by the Safety Review Committee, until at least 10 patients each are treated at each dose to determine the recommended Phase II dose.

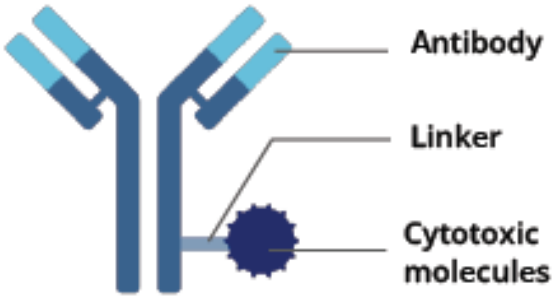
Exhibit II – LP-184 Phase Ia Clinical Trial Design[3]



Antibody Drug Conjugate Development

In mid-February, Lantern provided a roadmap for the development of antibody drug conjugates (ADCs) for targeted delivery of cytotoxic drugs to tumor cells. ADCs are a class of drug that binds to target cells using an antibody to deliver a toxin or other small molecule. The conjugate combines the specificity of monoclonal antibodies with the cytotoxic potency of chemotherapy drugs. ADCs consist of three components: an antibody, a linker, and a cytotoxic drug molecule. ADCs allow for the selective delivery of cytotoxic drugs to cancer cells while sparing normal cells, thereby reducing off-target toxicity and improving the efficacy of chemotherapy.

Exhibit III – Antibody Drug Conjugate[4]



[3] Source: Lantern Pharma 1Q:23 Corporate Presentation, May 9, 2023
[4] Source: Lantern Pharma 1Q:23 Corporate Presentation, May 9, 2023

The company plans to use its AI and ML platform to enhance the development of novel and effective ADCs for the targeted delivery of potent anti-cancer small molecules to cancer cells. The approach should improve the cost, pace and timeline of drug discovery and development through the use of its RADR platform. A roadmap was provided highlighting several features of the effort. These include use of algorithms to 1) predict optimal combinations of ADC components, 2) generate biomarker signatures that can predict a cancer's sensitivity to an ADC, 3) identify potential synergies and 4) predict the immunogenicity of ADC antibodies to cancer cell surface antigens. The strategy will enable the large-scale analysis of thousands of high-performing model features through their SHAP[5] scores to efficiently identify key genes and pathways that are mechanistically important to drug resistance, quality of patient outcomes, and improved delivery of ADC drug payloads.

ADCs have been in the news recently with the announcement of Pfizer's (PFE) plans to acquire Seagen (SGEN) for $43 billion. Formerly Seattle Genetics, Seagen is a pioneer in the development of ADCs, and has successfully commercialized three ADC assets including Adcetris, Padcev and Tivdak. Other recent acquisitions in the space include Gilead's (GILD) buy of Immunomedics and Merck's (MRK) acquisition of VelosBio.

Bielefeld University Collaboration

Lantern, in collaboration with Germany's Bielefeld University, is developing its AI platform to design cryptophycin antibody drug conjugates (ADCs).[6] Lantern's RADR will be used to develop ADCs that will provide it an exclusive worldwide license to develop and commercialize new candidates in the class. Lantern will use its ADC module along with research developed by Professor Norbert Sewald to design next-generation ADCs that offer potentially higher efficacy and more rapidly developed candidates at a lower cost. Initial work will be done with cryptophycins, which offer potency at pico-molar concentrations. The collaboration aims to de-risk the ADC development process and improve their creation. Under the terms of the collaboration, Dr. Sewald and his group will synthesize, optimize, and provide initial testing of the cryptophycin-ADCs.

Exhibit IV – Collaboration with Universität Bielefeld[7]



Professor Norbert Sewald, Ph.D.

- Professor of Organic and Bioorganic Chemistry at Bielefeld University (Bielefeld, Germany)
- Lead investigator of the European consortium Magicbullet::reloaded
- Research Focus
  - Development of antibody-drug and peptide-drug conjugates
  - Isolation and total synthesis of natural products
  - Chemical modification of bioactive peptides
  - Biocatalytic halogenation of amino acids, peptides, and proteins.

MAGIC BULLET :: Reloaded

Oncotarget Article

A June 26th release highlighted a publication which provided *in vitro* and *in vivo* data for LP-284 for mantle cell lymphoma (MCL), a subtype of non-Hodgkin's lymphoma (NHL). The article was published in Oncotarget and titled "LP-284, a small molecule acylfulvene, exerts potent antitumor activity in preclinical non-Hodgkin's lymphoma models and in cells deficient in DNA damage repair." The article noted that 20-40% of NHL patients experience relapse or refractory disease. This cancer represents and unmet need that may be addressed by LP-284 given the molecules differentiated mechanism of action.

The small molecule acylfulvene employs synthetic lethality to induce DNA double strand breaks and is able to be effective *in vivo* after developing resistance to bortezomib or ibrutinib which are proteasome and BTK inhibitors respectively. Bortezomib and ibrutinib are frequently used to treat NHL. Cells are sensitized to LP-284 when the molecule is used in combination with spironolactone, a hypertension drug. Failure to repair double strand breaks or

[5] A Shapley Additive Explanation (SHAP) score is a method for explaining the output of machine learning models by measuring the contribution of each input feature to the model's prediction. It is based on the Shapley value from cooperative game theory, which measures the marginal contribution of each player to a coalition.
[6] Cryptophycins are a class of cyclic depsipeptides with anticancer properties.
[7] Source: Lantern Pharma 2Q:23 Corporate Presentation, August 9, 2023

homologous recombination repair (HR) deficiency increases NHL cells' sensitivity to LP-284, targeting HR-deficient NHL patients with LP-284 is likely to produce better treatment outcomes.

The study the article was based on concluded that LP-284 is a novel and potent acylfulvene drug that can suppress tumor growth in NHL models and cells with HR or transcription coupled nucleotide excision repair (TC-NER) deficiency. LP-284 may be able to treat patients that are resistant to other lines of treatment, especially with certain genetic features. An investigational new drug (IND) application for LP-284 is expected to be filed in 2H:23 to begin a Phase I trial and pursue an indication in NHL.

AACR Presentation

Lantern presented at the American Association for Cancer Research (AACR) Annual Meeting in Orlando, Florida on April 19th, 2023. The abstract for the presentation reviews the role of DNA damage response (DDR) pathways and LP-184 in cancers that exhibit these characteristics. DDR pathways allow tumor cells to persist rather than undergo apoptosis. The abstract notes that up to a third of solid tumor cancers have a deficiency in the DDR pathways and they are vulnerable to DDR inhibitors allowing next generation acylfulvenes such as LP-184 to produce synthetic lethality in tumor cells. Synthetic lethality is a concept in oncology that refers to the idea that cancer cells that carry certain mutations or genetic alterations can be selectively killed by targeting a second, functionally related gene or pathway. LP-184 can be synthetically lethal due to its ability to cause unresolvable DNA damage if tumor cells express high prostaglandin reductase 1 (PTGR1)[8] and are deficient in nucleotide excision repair (NER) / homologous repair (HR) genes. Unlike poly ADP-ribose polymerase inhibitors (PARPi), LP-184 can induce cell death in both NER deficient as well as HR deficient cancers. Combination therapies with LP-184 and PARPi appear to provide compelling synergies where the former is able to force double DNA strand breaks in cancerous cells and the latter blocks their repair.

New Algorithm to Predict Blood Brain Barrier Permeability

Lantern's RADR artificial intelligence and machine learning platform has developed algorithms to predict the ability of a drug or compound to cross the blood-brain-barrier (BBB). The BBB blocks most compounds and pathogens that may circulate in the bloodstream while allowing in necessary nutrients and special molecules to pass. The algorithm has shown a prediction accuracy of 89-92% as reported by the company. It employs a combination of proprietary automated feature selection methods along with specialized hyper parameter optimization that integrates algorithms using an ensemble approach to quickly provide a compound's BBB permeability range. This approach allows for high throughput and ultra-fast BBB permeability analysis compared to traditional discovery and evaluation methods.

Lantern's RADR competed in a challenge that compared the output of the AI model against 1,975 compounds where the BBB permeability was known. Based on the results posted in the TD Commons Leaderboard, Lantern's RADR took the top four spots. Lantern's wholly owned subsidiary, Starlight Therapeutics which is focused on CNS cancers, will have access to the tool.

While explicit details on inputs were not provided in the press release, AI and ML models may be trained on the molecular weight, lipophilicity, and polar surface area of drugs, which are known to influence BBB permeability. Other approaches may learn complex patterns and relationships between drug properties and BBB permeability, and can make more accurate predictions than traditional machine learning models.

STAR-001

STAR-001 is the new designation for LP-184 when used in central nervous system (CNS) tumors under the Starlight Therapeutics banner. This asset is in preclinical development for multiple indications including glioblastoma (GBM), brain metastases in the lung, breast and skin, Atypical Teratoid Rhabdoid Tumors (ATRTs) and pediatric brain cancers. Several of these indications are eligible for orphan status including GBM, ATRT and pediatric brain cancers. ATRT has been granted a rare pediatric disease designation, which provides a priority review voucher if the pediatric indication is approved.

Favorable data has been observed for each of these indications. This includes the ability of STAR-001 to cross the blood brain barrier, induce tumor regression and offer potent efficacy in specific cancer cell lines. The drug is ame-

[8] PTGR1 is an enzyme that is involved in the metabolism of prostaglandins, which are small lipid molecules that play important roles in various physiological and pathological processes, including inflammation and cancer.

nable to combination therapies and has shown *in-vitro* potency with spironolactone. Lantern expects to progress the asset forward into Phase I/II adult and pediatric clinical trials over the next year.

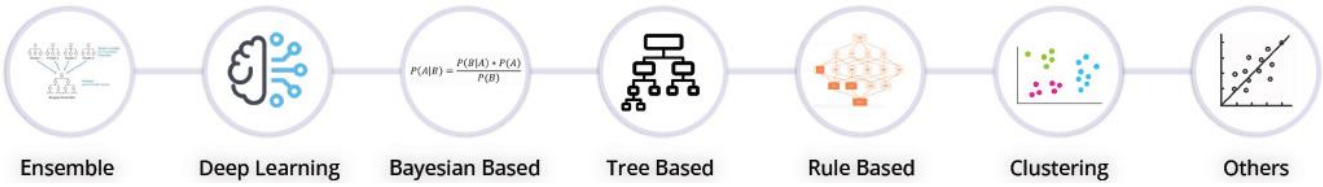
Exhibit V – Lantern Pipeline[9]



Milestones

- IND submission for LP-184 – May 2023
- Subject dosing, Stage 1 of Harmonic trial – 2Q:23
- ADC collaboration with Bielefeld University – June 2023
- Start of LP-184 Phase I trial in solid tumors – mid-2023
- Completion of IND-enabling studies for LP-284 – mid-2023
- IND submission for LP-284 – August 2023
- LP-284 trial start – 4Q:23

Exhibit VI – RADR's Algorithms[10]



Summary

Since our previous update, Lantern has further enrolled its HARMONIC study, received clearance for its LP-184 IND and completed IND enabling studies for LP-284. Collaborations continue, this time with Professor Sewald of Bielefeld University to develop ADCs. Lantern has further developed its portfolio and pipeline now featuring 12 programs that are being developed internally, with a partner or in a subsidiary. Our eyes remain fixed on the HARMONIC trial, which is the primary value driver for the company. Its indication in non-smoker NSCLC is an attractive niche which lacks other targeted therapies. We maintain our price target of $26.00 per share.

[9] Source: Lantern Pharma 2Q:23 Corporate Presentation, August 9, 2023
[10] Source: Lantern Pharma 1Q:23 Corporate Presentation, May 9, 2023

PROJECTED FINANCIALS

Lantern Pharma, Inc. - Income Statement

Lantern Pharma Inc.	2022 A	Q1 A	Q2 A	Q3 E	Q4 E	2023 E	2024 E	2025 E
Total Revenues ($US)	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
General & Administrative	$5,830	$1,733	$1,632	$1,479	$1,614	$6,458	$6,500	$6,581
Research & Development	$8,603	$2,553	$3,558	$3,211	$3,855	$13,177	$18,100	$18,643
Income from operations	($14,433)	($4,286)	($5,190)	($4,690)	($5,469)	($19,636)	($24,600)	($25,224)
Operating Margin								
Interest Income	$204	$134	$118	$19	$17	$288	$50	$10
Other Income	($32)	$285	$326	$0	$0	$611	$0	$0
Pre-Tax Income	($14,260)	($3,868)	($4,746)	($4,671)	($5,452)	($18,737)	($24,550)	($25,214)
Provision for Income Tax	$0	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*
Net Income	**($14,260)**	**($3,868)**	**($4,746)**	**($4,671)**	**($5,452)**	**($18,737)**	**($24,550)**	**($25,214)**
Reported EPS	**($1.31)**	**($0.36)**	**($0.44)**	**($0.43)**	**($0.50)**	**($1.72)**	**($2.01)**	**($2.02)**
Basic Shares Outstanding	10,851	10,857	10,857	10,860	10,900	10,869	12,200	12,500

Source: Company Filing // Zacks Investment Research, Inc. Estimates

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HISTORICAL STOCK PRICE

Lantern Pharma, Inc. – Share Price Chart[11]



[11] Source: Zacks Research System

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